

Serial No.: 10/691,117

Confirmation No.: 5330

Filed: October 21, 2003

For: SULFONATED STYRENE COPOLYMERS FOR MEDICAL USES

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**Remarks**

The Office Action mailed February 15, 2011 has been received and reviewed. No claims having been added, amended, or canceled herein, the pending claims are claims 15-17, 30-32, and 34-48.

Reconsideration and withdrawal of the rejections are respectfully requested in view of the following remarks.

**Rejection under 35 U.S.C. §102(b)**

The Examiner rejected claims 15-16, 38, and 48 under 35 U.S.C. §102(b) as being anticipated by Anders (CA 2,259,097). Applicants respectfully traverse the rejection.

Independent claim 15 recites a method that includes, among other things, forming a water-insoluble coating including at least one salt of a ***polysulfonated block copolymer*** hydrogel. Claims 16 and 38 depend from independent claim 15. Independent claim 48 recites a method that includes, among other things, forming a water-insoluble coating including at least one salt of at least one ***polysulfonated block copolymer*** hydrogel.

The Examiner alleged that Anders discloses a "polysulfonated block copolymer hydrogel" (page 3, line 2 of the Office Action mailed February 15, 2011). Applicants earnestly disagree.

Applicants respectfully submit that there is neither a teaching nor suggestion in Anders that the disclosed polysulfonated copolymers are ***block*** copolymers. Moreover, Applicants respectfully submit that one of skill in the art would recognize that the methods disclosed by Anders for preparing the polysulfonated copolymers would not lead to ***block*** copolymers. For example, page 3, lines 8-16; and page 10, lines 1-16 of Anders recite free radical polymerization methods that would lead, for example, to random copolymers or alternating copolymers, but not block copolymers. *See, for example,* "Copolymers" in Wikipedia (cited in the Supplemental Information Disclosure Statement submitted herewith), which teaches that a block copolymer such as "polystyrene-b-poly(methyl methacrylate) . . . is usually made by ***first*** polymerizing styrene, and then ***subsequently*** polymerizing MMA from the reactive end of the polystyrene chains. . . using ***living polymerization techniques***." (Page 2, bottom paragraph of "Copolymers"

in Wikipedia). Thus, Applicants respectfully submit that one of skill in the art would recognize that the free radical polymerization methods disclosed by Anders (i.e., which are not living polymerization techniques, and which do not sequentially polymerize the different monomers), would not reasonably be expected to lead to **block** copolymers. For at least this reason, Applicants respectfully submit that claims 15-16, 38, and 48 are not anticipated by Anders.

Reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) are respectfully requested.

**Rejections under 35 U.S.C. §103(a)**

A. The Examiner rejected claims 15-17, 34, 38-43, 45-46, and 48 under 35 U.S.C. §103(a) as being unpatentable over Anders (CA 2,259,097) in view of Cohen et al. (U.S. Patent No. 2,676,896). Applicants respectfully traverse the rejection.

**Claims 15-17, 34, 38-39, and 48**

The deficiencies of Anders as applied to independent claims 15 and 48 have been discussed herein above. In brief, Anders fails to teach or suggest polysulfonated **block** copolymers. Claims 16-17, 34, and 38 depend from claim 15.

Independent claim 39 recites a method that includes, among other things, forming a water-insoluble coating including at least one salt of a **polysulfonated block copolymer** hydrogel. Thus, the deficiencies of Anders as applied to independent claim 39 are similar to those discussed herein above with respect to independent claim 15.

Further, Applicants respectfully submit that the deficiencies of Anders are not corrected by Cohen et al., which fail to teach or suggest **block** copolymers.

For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 15-17, 34, 38-39, and 48 being obvious over Anders in view of Cohen et al.

**Claims 40-43 and 45-46**

Independent claim 40 recites a method that includes, among other things, forming a water-insoluble coating on the porous surface, wherein the water-insoluble coating includes at least one salt of a polysulfonated **hydrogel that is not chemically crosslinked**. Claims 42-43 and

45-46 depend directly or ultimately from claim 40. Notably, polymers disclosed in the present application (e.g., polysulfonated block copolymers) can form hydrogels without chemical crosslinking. *See, for example*, paragraph [0079] at pages 16-17 of the present specification.

It is unclear to Applicants' Representatives where, or if, the Examiner addressed the noted claim language in the remarks used to support the present rejection. However, the Examiner did state in the remarks to support the rejection of claims 15-16, 38, and 48 as being anticipated by Anders, that "Anders discloses the repeating units of the copolymers may originate directly from the cited monomers (A) and (B) (*not chemically crosslinked*) and from the cross-linking agent (C)" (page 3, lines 9-11 of the Office Action mailed February 15, 2011; emphasis added). To any extent that the Examiner is suggesting that Anders teaches or suggests a polysulfonated *hydrogel that is not chemically crosslinked*, Applicants earnestly disagree.

As discussed herein above, Anders discloses polysulfonated copolymers that are *not block* copolymers. Anders recites a "hydrophilic, water-swellable copolymer having repeating units of (A) at least one monomer that contains a sulfate and/or sulfonate group, (B) at least one monomer that contains a carboxyl and/or carboxylate group, and (C) at least one cross-linking agent that is at least bifunctional" (page 1, line 26 to page 2, line 3 of Anders). Thus, a cross-linking agent that is at least bifunctional is clearly required in the polymers disclosed in Anders.

Anders further teaches the importance of the at least bifunctional cross-linking agents to form the disclosed hydrogels. "The cross-linking agents (C) are preferably radically polymerizable compounds containing two to four olefin double bonds. Cross-linking agents with two olefin double bonds form two-dimensional networks, whereas higher-functional cross-linking agents result in three-dimensional networks that do not swell as much, and form hydrogels with less water." (Page 7, lines 19-24 of Anders). Thus, Anders teaches that the at least bifunctional cross-linking agents are required to form the two- or three-dimensional networks needed to form the disclosed hydrogels.

Thus, Applicants respectfully submit that Anders lacks a teaching or suggestion of a polysulfonated *hydrogel that is not chemically crosslinked*. Further, Applicants respectfully submit that the deficiencies of Anders are not corrected by Cohen et al., which fail to teach or suggest *block* copolymers.

For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 40-43 and 45-46 being obvious over Anders in view of Cohen et al.

**B.** The Examiner rejected claims 15-16, 30, 35-39, and 48 under 35 U.S.C. §103(a) as being unpatentable over Anders (CA 2,259,097) in view of Berlowitz-Tarrant et al. (U.S. Patent No. 5,840,387). Applicants respectfully traverse the rejection.

The deficiencies of Anders as applied to independent claims 15, 39, and 48 have been discussed herein above. In brief, Anders fails to teach or suggest polysulfonated *block* copolymers. Claims 16, 30, and 35-38 depend directly or ultimately from claim 15.

Nonetheless, the Examiner urges that "[o]ne skilled in the art at the time the invention was made would have been motivated to try sulfonated styrene-ethylene-butylene-styrene triblock copolymers taught by Berlowitz-Tarrant et al. in the copolymer hydrogels disclosed by Anders *because based on the description of the copolymers described by Anders, monomer (A) reads on a sulfonated styrene-ethylene-butylene-styrene triblock copolymer*" (page 11, lines 13-18 of the Office Action mailed February 15, 2011; emphasis added). Applicants disagree with the Examiner's assertion.

First, monomer (A) disclosed by Anders can be, amongst a wide variety of other things, a sulfonated styrene (e.g. page 6, lines 4-5 of the second paragraph of Anders). However, the Examiner's assertion that *monomer (A) reads on a sulfonated styrene-ethylene-butylene-styrene triblock copolymer* cannot be understood by Applicants' Representative, because a sulfonated styrene-ethylene-butylene-styrene triblock copolymer is a *polymer*, not a *monomer*.

Second, as discussed herein above, Anders fails to teach or suggest polysulfonated *block* copolymers. Thus, Applicants respectfully submit that the Examiner's reasoning fails to rationally explain why one of skill in the art would be motivated to try a sulfonated styrene-ethylene-butylene-styrene *triblock* copolymer as disclosed by Berlowitz-Tarrant et al.

For at least these reasons, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for claims 15-16, 30, 35-39, and 48 being unpatentable over Anders in view of Berlowitz-Tarrant et al.

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C. The Examiner rejected claims 15-16, 31-32, 40, and 44-47 under 35 U.S.C. §103(a) as being unpatentable over Anders (CA 2,259,097) in view of Shalaby (U.S. Patent No. 6,413,539). Applicants respectfully traverse the rejection.

**Claims 15-16 and 31-32**

The deficiencies of Anders as applied to independent claim 15 have been discussed herein above. In brief, Anders fails to teach or suggest polysulfonated **block** copolymers. Claims 16 and 31-32 depend directly or ultimately from claim 15.

Shalaby discloses **polyester** block copolymers. However, Shalaby fails to teach or suggest **polysulfonated** copolymers, much less **polysulfonated block** copolymers. Thus, Applicants respectfully submit that the deficiencies of Anders are not corrected by Shalaby.

For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 15-16 and 31-32 being obvious over Anders in view of Cohen et al.

**Claims 40 and 44-47**

The deficiencies of Anders as applied to independent claim 40 have been discussed herein above. In brief, Anders lacks a teaching or suggestion of a polysulfonated **hydrogel that is not chemically crosslinked**.

Shalaby discloses "hydrogel-forming, self-solvating, absorbable polyester copolymers" (abstract of Shalaby). However, Shalaby fails to teach or suggest **polysulfonated** polyester copolymers, much less **polysulfonated hydrogels**. Thus, Applicants respectfully submit that the deficiencies of Anders are not corrected by Shalaby.

For at least this reason, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of unpatentability for claims 40 and 44-47 being obvious over Anders in view of Shalaby.

Reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

**Amendment and Response**

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**Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

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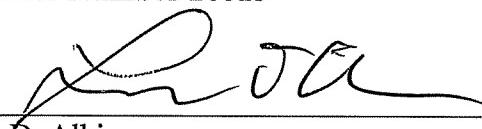
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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **Amendment**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 13<sup>th</sup> day of May, 2011.

By:

Name:

